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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,124

08/07/2006

Jeffrey H. Burbank

T4342-14264US01

6407

181 7590 05/22/2009

MILES & STOCKBRIDGE PC
1751 PINNACLE DRIVE
SUITE 500
MCLEAN, VA 22102-3833

EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

NOTIFICATION DATE

DELIVERY MODE

05/22/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocketing@milesstockbridge.com
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Office Action Summary	Application No. 10/544,124	Applicant(s) BURBANK ET AL.	
	Examiner LESLIE R. DEAK	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-18 and 29-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27 is/are rejected.
- 7) ☒ Claim(s) 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/05, 1/11/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1-18 and 29-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 March 2009.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 19, 20, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,247,434 to Peterson et al.

In the specification and figures, Peterson discloses the apparatus as claimed by Applicant. With regard to claim 19, Peterson discloses a waste balancing system for an extracorporeal blood treatment apparatus comprising a first container 132 with fluid waste, second container 130 with a replacement fluid, pressure sensor 52 in pressure communication with the containers, and a controller 500 that controls a pump 42 based on measurements from the pressure sensor (see columns 5, 8). With regard to Applicant's recitation that the containers are "in a stacked relationship," Applicant has not provided a specific definition for this "stacked" relationship. It is the position of the

Examiner that "stacked" may include a side-by-side orientation, as illustrated by Peterson. Accordingly, the Peterson disclosure meets the limitations of the claim.

With regard to claim 20, Peterson discloses a second pressure sensor 54 that may be used to detect a drop in pressure, indicating the emptying of one of the containers.

With regard to claim 22, it is the position of the Examiner that since the pressure sensor disclosed by Peterson is connected to controller 500, it is capable of being adjusted, meeting the limitations of the claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 21, 23, 25, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,247,434 to Peterson.

In the specification and figures, Peterson discloses the apparatus substantially as claimed by Applicant with the exception of the position of the containers on top of one another. Peterson discloses that the pressure of one container against another creates a pressure differential that drives fluid movement. Positioning the containers on top of one another provides a similar pressure differential. It is the position of the Examiner

Art Unit: 3761

that placing the containers on top of one another, absent any claimed structure that operates the containers differently than when they are side by side, is not a patentable improvement over the prior art.

With regard to claims 23, 25, and 26, Peterson discloses a blood treatment apparatus comprising a dialyzer wherein the fluid handling components are part of a removable cartridge. With regard to Applicant's limitation drawn to a "support" that places the containers in a configuration such that a pressure measurement is indicative of the weight of the containers and their contents, it is the position of the Examiner that the housing of equalizer 54 provides such a relationship. When the density of fluid and volume of a container are known, a pressure measurement may be manipulated to arrive at a measurement of the weight of the containers. The support claimed by Applicant does not add any structural limitation that distinguishes over the prior art.

With regard to claim 27, Peterson discloses that the containers may be expandable since the membrane fluctuates depending on the amount of fluid in each chamber.

6. In the alternative to the rejections presented above, claims 19-24, 26, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,247,434 to Peterson in view of US 2001/0037079 to Burbank et al.

In the specification and figures, Peterson suggests the apparatus substantially as claimed by Applicant.

With regard to claim 19, Burbank discloses that the waste receptacle 36 is placed on top of replacement fluid container 42, teaching the stacked configuration claimed by Applicant. Such stacking allows a single weight sensor to measure the net fluid change in the patient.

With regard to claim 23, Burbank's support structure allows for vertical stacking of the containers. When combined with the pressure sensor of Peterson, Burbank's vertical stacking allows a pressure measurement in the lower container to indicate the weight of both containers.

With regard to claims 24 and 26, Burbank discloses that the assembly may comprise a hemofilter, and the entire assembly may be disposable.

Allowable Subject Matter

7. Claim 28 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. The following is an examiner's statement of reasons for indicating allowable subject matter: The prior art fails to suggest the combination of elements claimed by Applicant. In particular, the prior art fails to disclose a blood treatment system with a balancing apparatus that comprises a piston between a waste container and a replacement fluid container. The prior art teaches volumetric balancing systems that use flexible membranes in a side-by-side configuration, but does not teach or suggest the use of a piston between the containers.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761